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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,099	02/06/2007	Shuji Terashima	P29763	9412

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EXAMINER	
POPA, ILEANA	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
07/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,099	TERASHIMA ET AL.	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *19-29 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 30-33* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/20/2007; 10/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I, drawn to a method of preparing a cell concentrate, and of the species of non-woven fabric in the reply filed on 04/29/2008 is acknowledged. The traversal is on the ground(s) that the Office has failed to establish a lack of unity of invention. Applicants note that this application was filed under 35 U.S.C. § 371, and unity of invention rules apply. To establish a lack of unity of invention, the Office is required to show how the claims fail to share a corresponding special technical feature, which distinguishes the claims from the prior art. Applicants note that claims 19 and 21-29 are dependent upon claim 1, and require all of the elements of claim 1, and therefore must share at least those special technical features that claim 1 includes. Applicants respectfully submit that at least with regard to claims 19 and 21-29, unity of invention cannot be found lacking, and request that Office withdraw the restriction at least with regard to these claims. With regard to the election of species requirement, Applicants note that the various types of filters are disclosed as examples of the present invention. Applicants submit that there is no basis under unity of invention rules to separate species based upon theories of independence or distinctness, as the Office Action does. Applicants request withdrawal of the election of species requirement as well.

This is not found persuasive because, beside lack of a corresponding special technical feature, there are other considerations on which lack of unity can be

established, for example when the claims are directed to multiple methods (see the restriction requirement mailed on 02/28/2008). In the instant case, the Office is not required to show how the claims fail to share a corresponding special technical feature because the claims are drawn to multiple methods and therefore, lack unity. Although claims 19 and 21-29 are dependent from claim 1 and require all of the elements of claim 1, claims 19 and 21-29 recite additional limitations which necessitate additional searches in the patent and non-patent literature and additional considerations under different statutes. Along these lines, it is noted that a search for the elected invention failed to provide references teaching the limitations of claims 19-29. Therefore, examining claims 19 and 21-29 together with the elected invention would be a burden for the Examiner.

Since a search for the invention of Group I yielded results relevant for the different species of materials recited in claims 14, 16, and 18, the species election requirement between the species of non-woven fabric, sponge, or a combination of non-woven fabric and sponge is hereby withdrawn.

The restriction requirement between the inventions of Groups I and II is still deemed proper and is therefore made FINAL.

Claims 19-29 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-18 and 30-33 are under examination.

Priority

2. It is acknowledged that a certified foreign priority paper has been received. However, an English translation has not been provided. Correction is required.

Should Applicants provide a certified translation of their foreign priority document to overcome the prior art rejection, Applicants should indicate whether the priority application is identical to the instant application, or if the priority application contains additional disclosure. If there is additional disclosure, a brief summary should be provided. Applicants should also indicate where support for each of the claim limitations (for the independent claims) can be found in the translated priority document by page and line number. If support is not found *in ipsis verbis*, clarification on the record may be helpful to the examination process.

Information Disclosure Statement

3. The IDS forms of 06/20/2007 and 10/12/2006 have been considered. It is noted that the foreign document 2000-325071, 2000-166541, 11-56351, 11-206875, 10-201470, 57-83284, and 10-137557 have been lined through because Applicant did not provide an English translation of the documents, nor did Applicant provide English abstracts. Additionally, since no English translation has been provided, the foreign documents WO 02/101029 and WO 02/087660 were only considered with respect to their abstract.

Claim Objections

4. Claim 12 is objected to because of the following informalities: the claim recites "introducing the cell-containing solution from the inlet therefor". Appropriate correction to "therefore" is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 12-17 of U.S. Patent No. 6,268,119 in view of each Oka et al. (U.S. Patent NO 5,298,165), Oka et al. (PGPUB 2004/0251195, Applicant's IDS), Fukuda et al. (WO 02/087660, Abstract, Applicant's IDS), and Rubinstein et al. (Proc Natl Acad Sci USA, 1995, 92: 10119-10112, Applicant's IDS).

The instant claims are drawn to a method of preparing a concentrate of nucleated cells by introducing a cell-containing solution which contains both nucleated cells and unnecessary cells into a filter device comprising an inlet and an outlet, wherein the filter device capture the nucleated cells and discharges the unnecessary cells, followed by the addition of a recovery solution to recover the nucleated cells captured by the filter; before being introduced into the filter device, the cell-containing solution is separated into a layer rich in nucleated cells, a nucleated cell-diluted layer (i.e., plasma), and a layer rich in unnecessary cells, wherein the layer rich in unnecessary cells is the first to be introduced into the filter device, followed by nucleated cell-diluted layer and the layer rich in nucleated cells in this order; the recovery solution could be the nucleated cell-diluted layer (i.e., plasma) and the recovery solution is further centrifuged to concentrate the nucleated cells (claims 1, 7-10, and 30-33). Separation of the cell-containing solution into layers takes place by centrifugation or by agglutination with hydroxyethyl starch (HES) followed by centrifugation (claims 2, 3, and 6), the unnecessary cells are erythrocytes, and the nucleated cells are hematopoietic stem cells (claims 4 and 5). The filter device further contains an aggregate-capturing material between the inlet and the filter and a porous recovery solution-rectifying material between the filter and the outlet; the filter and the recovery solution-rectifying material form a porous filter material wherein the value obtained by dividing the effective filtration area of the filter material by the thickness of the nucleated cell-capturing filter is between 15 and 120 cm (claims 11-13). The filter material is non-woven fabric (having an average fiber diameter of 1.1-3.0 μm for the cell-capturing material or 0.5-1.5 μm for

the rectifying material, with a packaging density of 0.1-0.3 g/cm^3), a sponge-like structure (having an average pore diameter of 7-25 μm for the cell-capturing material or of 2-10 μm for the rectifying material, with a porosity between 55 and 90%), or a combination of a non-woven fabric with a sponge-like structure (claims 14-18).

The patent claims recite a cell separation method comprising introducing a fluid containing cells to be recovered and cells to be removed into a cell-capturing device having an inlet and an outlet and a cell-capturing means which captures the cells to be recovered and discharges the cells to be removed, followed by the introduction of a liquid into the cell-capturing means to recover the captured cells; the cell-capturing means comprises non-woven fabrics with a fiber diameter of 1.0-30 μm or porous spongy structure having a pore size of 2.0-25 μm (claims 1, 6, and 12). The cells to be recovered are nucleated cells such as hematopoietic stem cells and the cells to be removed are erythrocytes (claims 13-17). The specification defines that the liquid used to recover the captured cells could be plasma (p. 8, lines 21-51, p. 12, line 63 through lines 1-5 of p. 13). The patent claims do not recite a composite filter comprising an aggregate-capturing material, a nucleated cell-capturing material, and a recovery solution rectifying material, nor do they recite using centrifugation to separate the cell-containing solution into a layer rich in nucleated cells, a nucleated cell-diluted layer, and a layer rich in unnecessary cells before introducing it into the filter device or adding HES before centrifuging the cell-containing solution. However, at the time the invention was made, such limitations were well known and used in the prior art. For example, Oka et al. (U.S. Patent NO 5,298,165) teach improved leukocyte capturing by using a

composite filter comprising a pre-filter (i.e., an aggregate-capturing material), a nucleated cell-capturing filter, and a microfilter, in this order (Abstract, column 8, lines 25-45, column 10, lines 19-30 and 62-67, column 11, lines 1-16). It is noted that the instant specification defines the recovery solution rectifying material as a porous filter having a packing density of 0.1-0.3 g/cm^3 and an average fiber diameter of 0.5-1.5 μm (p. 19, second full paragraph). Since Oka et al. (U.S. Patent NO 5,298,165) teach their microfilter as having a packing density of 0.15-0.38 g/cm^3 and a fiber diameter of 0.5-1.4 μm (column 8, lines 60-66, column 12, lines 53-55), their microfilter has the same properties as the claimed recovery solution rectifying material, i.e., their microfilter is a recovery solution rectifying material. In addition, both Oka et al. (PGPUB 2004/0251195) and Fukuda et al. teach a method for isolating nucleated cell from blood, the method comprising centrifuging the blood, i.e., separating the blood into a buffy coat (layer rich in nucleated cells), plasma (nucleated cell-diluted layer), and an erythrocyte pellet (layer rich in unnecessary cells), followed by introducing the separated blood into a filter device, wherein such a separation results in high retention of nucleated cells on the filter (see Oka et al., p. 1, paragraphs 0005 and 0010; Fukuda et al., Abstract). Rubinstein et al. teach adding HES to blood to enhance erythrocyte sedimentation (p. 10120, column 2, third paragraph). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the patent claims by introducing the HES/centrifugation steps and using a composite filter as taught by the prior art, with a reasonable expectation of success. One of skill in the art would have been motivated to do so because the art teaches that such modifications result in increased retention of

nucleated cells within the filter device. With respect to the different values recited in the instant claims 11, 12, 15, and 17, it would have been obvious to one of skill in the art to vary the parameters (i.e., fiber or pore size and packaging density) to optimize the results according to the nucleated cell to be separated. With respect to centrifuging the recovery solution, it would have been obvious to one of skill in the art to do such in order to further concentrate the recovered nucleated cells. With respect to using a combination between a non-woven and a sponge-like material, it would have been obvious to one of skill in the art to do so in order to improve the performance of the filter device. With respect to the limitation of the recovery solution being nucleated cell diluted layer (i.e., plasma, see above), since the specification defines that the recovery solution could plasma, it would have been obvious to one of skill in the art to use such a layer to achieve the predictable result of recovering the nucleated cells. Thus, the instant claims and patent claims are obvious variants.

7. Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-17 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumita et al. (U.S. Patent No. 6,268,119, Applicant's IDS), in view of each Oka et al. (U.S. Patent No. 5,298,165), Fukuda et al. (WO 02/087660, Abstract, Applicant's IDS), Oka et al. (PGPUB 2004/0251195, Applicant's IDS), and Rubinstein et al. (Proc Natl Acad Sci USA, 1995, 92: 10119-10112, Applicant's IDS).

Sumita et al. teach a method of preparing a nucleated cell concentrate by introducing blood into a filter device comprising a filter material capable of capturing nucleated cells and discharging unnecessary cells, followed by the introduction of a recovery solution to elute the captured nucleated cells; the filter material could be a non-woven fabric with a diameter of 1-30 μm or a spongy structure with a pore size of 3-20 μm, the nucleated cells are hematopoietic stem cells, the unnecessary cells are erythrocytes, and the recovery solution could be plasma (claims 1, 4, 5, 30, 32, and 33) (column 2, lines 51-67, column 3, lines 1-8 and 50-55, column 5, lines 18-67, column 6, lines 27-60, column 8, lines 21-51, p. 12, line 63 through lines 1-5 of p. 13).

Sumita et al. do not teach a composite porous filter material comprising, in a direction from the inlet to the outlet, an aggregate-capturing material, a nucleated cell-capturing material, and a recovery solution-rectifying material, wherein the filter material

comprises a non-woven fabric, a sponge-like structure, or a combination between a non-woven fabric and a sponge-like structure (claims 11-17). Oka et al. (U.S. Patent NO 5,298,165) teach improved leukocyte capturing by using a porous composite filter made of a non-woven material comprising in the upstream to downstream order: a pre-filter (i.e., an aggregate-capturing material), a nucleated cell-capturing filter, and a microfilter (Abstract, column 8, lines 25-45, column 10, lines 19-30 and 62-67, column 11, lines 1-16). The porous composite filter of Oka et al. (U.S. Patent NO 5,298,165) has an average fiber diameter of 1.0-2.0 for the nucleated cell-capturing material and of 0.5-1.4 μm for the microfilter material and a packing density of 0.15-0.38 g/cm^3 (claim 15) (column 8, lines 60-66, column 10, lines 19-30). With respect to the limitation of recovery solution rectifying material, it is noted that the instant specification defines the recovery solution rectifying material as a porous filter having a packing density of 0.1-0.3 g/cm^3 and an average fiber diameter of 0.5-1.5 μm (p. 19, second full paragraph). Since Oka et al. (U.S. Patent NO 5,298,165) teach their microfilter as having a packing density of 0.15-0.38 g/cm^3 and a fiber diameter of 0.5-1.4 μm (column 8, lines 60-66, column 12, lines 53-55), their microfilter has the same properties as the claimed recovery solution rectifying material, i.e., their microfilter is a recovery solution rectifying material. Therefore, Oka et al. (U.S. Patent NO 5,298,165) teach a porous composite filter comprising in a direction from the inlet to the outlet, an aggregate-capturing material, a nucleated cell-capturing material, and a recovery solution-rectifying material. It would have been obvious to one of skill in the art, at the time the invention was made, to modify the filter device of Sumita et al., by using the composite filter device of Oka et

al. (U.S. Patent NO 5,298,165), with a reasonable expectation of success. The motivation to do so is provided by Oka et al. (U.S. Patent NO 5,298,165), who teach that composite filters are very efficient in removing nucleated cells from blood. One of skill in the art would have been expected to have a reasonable expectation of success in doing so because the art teaches that composite filters can be successfully used to capture blood nucleated cells. With respect to the limitations recited in claim 17, Oka et al. (U.S. Patent NO 5,298,165) teach an average pore diameter of 6-20 μm for the nucleated cell-capturing material, of 4-12 μm for the recovery solution-rectifying material and a packing density of 0.15-0.38 g/cm^3 (column 10, lines 41-45, column 12, lines 53-55). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to modify the sponge-like filter of Sumita et al. according to the teachings of Oka et al. (U.S. Patent NO 5,298,165) to achieve the predictable result of obtaining a composite sponge-like filter with improved properties.

Sumita et al. and Oka et al. (U.S. Patent NO 5,298,165) do not teach using centrifugation to separate the cell-containing solution into a layer rich in nucleated cells, a nucleated cell-diluted layer, and a layer rich in unnecessary cells before introducing it into the filter device or adding HES before centrifuging the cell-containing solution (claims 1-3 and 6-8). However, at the time the invention was made, such limitations were well known and used in the prior art. For example, both Oka et al. (PGPUB 2004/0251195) and Fukuda et al. teach a method for isolating nucleated cell from blood, the method comprising centrifuging the blood with the simultaneous introduction of the separated components into nucleated cell-capturing filters, wherein the method results

in high retention of nucleated cells on the filter (see Oka et al., p. 1, paragraphs 0005 and 0010, p. 2, paragraph 0017; Fukuda et al., Abstract). Such a method would necessarily result in a cell gradient comprising a buffy coat at the top (layer rich in nucleated cells), plasma in the middle (nucleated cell-diluted layer), and an erythrocyte pellet at the bottom (layer rich in unnecessary cells) with the introduction into the filter of the separated components in the order of erythrocyte pellet first, plasma second, and buffy coat third (claims 1, 7, and 8). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the method of Sumita et al. and Oka et al. (U.S. Patent NO 5,298,165) by introducing into the filter device a blood cell gradient as taught by Fukuda et al. and Oka et al. (PGPUB 2004/0251195), with a reasonable expectation of success. The motivation to do so is provided by Fukuda et al., who teach that such a method results in high retention of nucleated cells on the filter (Abstract). One of skill in the art would have been expected to have a reasonable expectation of success in doing so because the art teaches that such steps can be successfully used to obtain nucleated cells from blood. Sumita et al., Oka et al. (U.S. Patent NO 5,298,165), Fukuda et al., and Oka et al. (PGPUB 2004/0251195) do not teach using HES in combination with centrifugation (claims 3 and 6). Rubinstein et al. teach adding HES to blood to enhance erythrocyte sedimentation (p. 10120, column 2, third paragraph). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the method of Sumita et al., Oka et al. (U.S. Patent NO 5,298,165), Fukuda et al., and Oka et al. (PGPUB 2004/0251195) by introducing the HES before the centrifugation step, with a reasonable expectation of success. One of

skill in the art would have been motivated to do so in order to improve separation of blood into its components. One of skill in the art would have been expected to have a reasonable expectation of success in doing so because the art teaches that HES improves erythrocyte elimination. With respect to the limitation of the filter having value obtained by dividing the effective filtration area by the thickness of the nucleated cell-capturing material of 15-120 cm (claims 11 and 12) or of porosity of 55-90% (claim 17), it would have been obvious to one of skill in the art to use routine experimentation to vary these parameters to optimize the results according to the nucleated cell to be separated (see Oka et al., U.S. Patent NO 5,298,165, column 6, lines 3-9). With respect to centrifuging the recovery solution (claim 10), it would have been obvious to one of skill in the art to do such in order to further concentrate the recovered nucleated cells. With respect to the limitation of the recovery solution being nucleated cell diluted layer (claim 9), since Sumita et al. teach that plasma can be used s a recovery solution and since the nucleated cell diluted layer is plasma (see above), it would have been obvious to one of skill in the art to use such a layer to achieve the predictable result of recovering the nucleated cells.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

10. Claims 1-18 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumita et al. taken with each Oka et al. (U.S. Patent NO 5,298,165),

Fukuda et al., Oka et al. (PGPUB 2004/0251195), and Rubinstein et al., in further view of Tanaka et al. (U.S. Patent No. 6,048,464).

The teachings of Sumita et al., Oka et al. (U.S. Patent NO 5,298,165), Fukuda et al., Oka et al. (PGPUB 2004/0251195), and Rubinstein et al. are applied as above for claims 1-17 and 30-33. Sumita et al., Oka et al. (U.S. Patent NO 5,298,165), Fukuda et al., Oka et al. (PGPUB 2004/0251195), and Rubinstein et al. do not teach a filter made from a combination of non-woven fabric with a sponge-like structure (claim 18). However, at the time the invention was made, such combination filters were taught by the prior art. For example, Tanaka et al. teach a nucleated cell-capturing filter comprising both a sponge-like structure and a non-woven fabric (Abstract, column 3, lines 19-46, column 6, lines 17-26). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the method of Sumita et al., Oka et al. (U.S. Patent NO 5,298,165), Fukuda et al., Oka et al. (PGPUB 2004/0251195), and Rubinstein et al. by using a combination filter comprising both a sponge-like structure and a non-woven fabric to achieve the predictable result of capturing nucleated cells.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

11. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD
/Ileana Popa/
Art Unit 1633